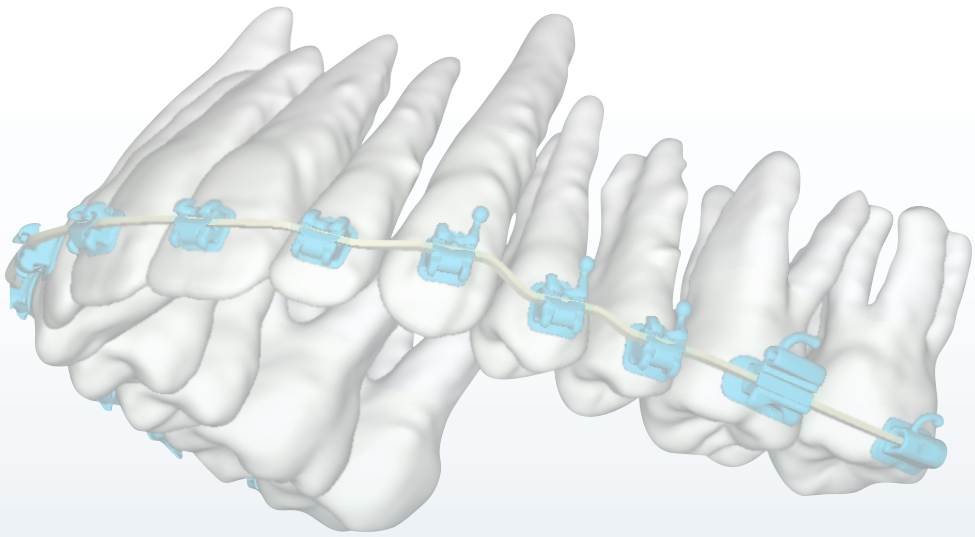
suresmile®



Hardware Manual

suresmile®

Hardware Reference Manual

ORAMETRIX®

OraMetrix has its headquarters in Richardson, Texas, with offices in Berlin, Germany.
For more information about OraMetrix, call +1.972.728.5500 or visit the OraMetrix website at www.orametrix.com. To learn more about SureSmile, go to www.suresmile.com.

For SureSmile customer support, supplies, or other questions, please call SureSmile Customer Care:

Location	Phone Number	Hours
United States & Canada	**1.888.672.6387**	Monday - Friday 7am-7pm (U.S. Central Time)
Australia	**1.800.976.453**	Monday - Friday 9am-6pm (Australian Eastern Time)
Dubai/United Arab Emirates	**+ 1.972.728.5904**	Monday: 6am-11am Tuesday-Friday: 6am-11am & 4pm-midnight (Gulf Standard Time)
Europe	**+ 1.972.728.5902**	Monday: 7am-9am Tuesday-Friday: 7am-9am & 2pm-midnight (Central European Time)
Japan	**+ 1.972.728.5903**	Monday-Friday 8am-5pm (Japan Standard Time)
All other countries	**+ 1.972.728.5900**	Monday-Friday 7am-7pm (U.S. Central Time)

You can also e-mail customer support at **customer.care@orametrix.com**

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DOC-500105-8

Acknowledgments

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1. Safety

1.1 Symbols used on product labels

	Non sterile
	For Single use only. Do not reuse.
	Consult instructions before use! This symbol advises the reader to consult the operating instructions for information needed for the proper use of the device.
	WARNING: To avoid risk of injury from electric shock, do not open the enclosure. This symbol indicates the presence of electric shock hazards. Enclosures marked with these symbols should only be opened by an OraMetrix authorized service provider.
	Maximum Load
	Type B applied part (equipment intended to come into contact with the patient).

1.2 Symbols used in this manual

	WARNING Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury**.**
	CAUTION Indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury, product or property damage. It may also be used to alert against unsafe practices.
	NOTICE Indicates important information that is required to use the system properly.

1.3 Safety Precautions

The primary concern of OraMetrix is that the SureSmile System equipment is operated and maintained for the safety of the patient and staff.

The SureSmile System includes dental imaging equipment and must therefore be used only under the supervision of qualified dental staff.

The user bears legal responsibility related to the possession and use of the equipment.

OraMetrix staff or a third party authorized by OraMetrix will install the SureSmile system equipment and are allowed to perform technical service.

To ensure safe and reliable operation of the equipment, the operator must read and understand this manual before attempting to operate the SureSmile System.

Operators must be well trained to safely and properly use the system.

Operators should strictly follow the proper cleaning instructions, as detailed in this manual, to avoid damaging the Scanning Station or other SureSmile equipment.

<table>
<tr><td rowspan="3">NOTICE
 </td><td>The equipment must be used in compliance with the procedures contained in the SureSmile system user manuals. The equipment should never be used for purposes other than as described in the user manual.
For additional system information, see:
SureSmile Online Help
SureSmile Practice Reference Manual
Tooth Preparation Kit Insert</td></tr>
<tr><td>OraMetrix shall NOT be responsible for:
Any use of the SureSmile equipment other than for its intended use;
Any damage to the equipment that the user causes by incorrect maintenance not in compliance with the procedures contained in the relevant user’s and installation manuals provided with the equipment, or by incorrect operation techniques; or
Any mechanical and/or electrical modifications made after installation.</td></tr>
<tr><td>OraMetrix does not determine patient care. OraMetrix provides therapeutics as directed by the doctor. The best possible results from the SureSmile process depend on the application of the doctor’s diagnostic and clinical judgment.</td></tr>
</table>

1.3.1 Operational

WARNING	Patients might choke on the OraScanner mirror if the mirror detaches. Do not use damaged mirrors.
	Do not use the equipment for patients with uncontrolled biting behavior.

CAUTION	Hazards related to incorrect treatment planning or archwires are possible. A trained user must control all SureSmile software, data acquisition, and appliance-related functions.
	The operator and patients should not look directly into the flashing light of the OraScanner.
	An operator might probe too deeply with the OraScanner mirror and cause a gag reflex.
	A patient might choke if the OraScanner cord wraps around them.

NOTICE	A trained operator must apply SureWhite properly so that the scanned image is of acceptable quality. For more detailed information, see the paper insert in the SureSmile Tooth Preparation Kit.
	The operator will touch the patient's gums, which might result in soreness. Proper operator training should minimize patient discomfort.
	The OraScanner unit is not intended for use as an operative device and is not manufactured to be sterile.

1.3.2 Environmental

WARNING	Do not place the SureSmile Server and the network infrastructure in the patient contact area. It is not designed, tested, or specified for use in patient contact areas.
	The SureSmile System is not designed for use in environments where oxygen-rich or explosive gasses are present. Do not locate the equipment in such an area.
	Do not use the equipment in the presence of flammable anesthetics.

1.3.3 Equipment

WARNING	Do not use an extension cord or a multiple-outlet power cord to power the Scanning Station.
	The Scanning Station must only be connected to a power source (electrical outlet) with proven earth ground (hospital-grade receptacle), or with comparable safety.
	A cable with signs of wear or damage must not be used or repaired; it must be replaced.
	Do not make mechanical, electrical, or configuration modifications to the equipment.
	Do not connect any additional device (e.g. monitor, printer, external drives, hard drives, other networks) to any interface (keyboard, mouse, audio, printer, serial-port, USB, Firewire, VGA or DVI) of the Scanning Station's PC. Any additional electrical connection may disable the safety protection of the Scanning Station, and may lead to harmful electrical injuries to patients or bystanders.
	Do not connect any Scanning Station internal component directly to main power. Injury to patients could result.
	Do not connect the LAN cable directly to the Scan Station computer. Use only the original SureSmile® LAN cable to connect the LAN to the special external LAN connector.
	Never push objects of any kind through openings in the equipment. Dangerous voltages may be present. Conductive foreign objects could produce a short circuit that could cause fire, electric shock, or damage to your equipment.
	To avoid short circuits and corrosion, do not allow any liquids to penetrate the inside of the equipment.
	Do not place open containers with liquids on the Scanning Station.

CAUTION	It is very important to be careful with the fiber-optic cable. Do not bend, pinch, or crimp the cable. Do not pull on the OraScanner handheld piece to move the Scanning Station.
	Use caution when moving the SureSmile System equipment. This precision-measuring device should be handled with care. Failure to follow proper transportation procedures may result in damage to the system and risk of personal injury.
	Use only cleaning solutions approved by OraMetrix to disinfect a SureSmile mirror. See section 2.7.2 for a list of approved solutions.
	To avoid scratching or damaging OraScanner mirrors, do not soak them with other instruments.
	Do not soak an OraScanner mirror in approved cleaning solutions beyond the manufacturer's recommended time for a high-level disinfection. It is not necessary to soak the OraScanner mirror to the point of sterilization. Soak times past 90 minutes may degrade the mirror, potentially causing risk to patients.
	Do not place an OraScanner mirror in an ultrasonic cleaning unit. Ultrasonic cleaning will erode the mirror adhesive over time.
	Do not sterilize an OraScanner mirror in an autoclave.
	Do not hang anything from the Scanning Station monitor's extension arm. Adjust the extension arm gently.
	Do not step on the power cord and network cables.

2. System & Equipment

2.1 SureSmile Overview

SureSmile is the first end-to-end system for fixed appliances that allows an orthodontist to apply 3-D diagnostic imaging and computer-aided treatment planning to unlock the power of shape memory alloy archwires through customization. This results in greater control and efficiency for orthodontic care.

SureSmile is comprised of several key components:

- The **OraScanner**, a unique, patented, handheld, intraoral, imaging device that uses white light (not lasers or x-rays) to capture 3-D images of a patient's dentition. The OraScanner captures the images of teeth at a chairside station, allowing the operator to view the resulting models as they are being made.

  Additionally, a practice can use a **SureSmile-certified CBCT Scanner** in their practice or at an imaging facility to capture 3-D images of a patient's dentition.

- **SureSmile 3-D software** provides powerful visualization tools for precision diagnosis, treatment simulation, and customized appliance design. The doctor can review the digital setup with this software and use it to communicate with patients and the Digital Lab at OraMetrix.

- The **Digital Lab** provides scan and setup processing to produce precise robotically bent archwires.

2.2 System Overview

The diagram on the following page illustrates the equipment required to support the SureSmile Process. There are two possible system configurations:

- **SureSmile Complete Package** – includes at least one Scanning Station
- **SureSmile Service Package** – does not include a Scanning Station; practice will order models based on CBCT scans or impressions

SureSmile software can also be installed on a doctor's office and home computers, as long as these computers meet the minimum system requirements for SureSmile.

The following table describes the purpose and source of equipment installed at a typical SureSmile practice.

Table 1: SureSmile Equipment for Typical Practice

Component	Description	Manufacturer*
Scanning Station (optional)	A mobile cart containing a computer and OraScanner. (If scanning is required at a site, there will be one or more Scanning Stations)	**OraMetrix**
SureSmile Server with UPS	The server located in the back office that houses the database of SureSmile patients and connects the practice's Scanning Stations to OraMetrix. (One per site)	**Dell**
Firewall including router (ASA)	A small device that connects the SureSmile Server to the public network and prevents unauthorized outside access to patient files. The firewall also connects the practice network to the SureSmile network to support treatment planning on practice-owned computers and acquisition of photos/x-rays.	**Cisco**

*manufacturer subject to change

With the exception of the Scanning Station, all of equipment in Table 1 is required for a functional SureSmile site. Additional sites without a Scanning Station can be set up to enable the doctor to work on SureSmile patients at home or at a satellite office.

SureSmile patient information is collected at a practice and delivered over a high-speed connection (usually DSL) to OraMetrix's headquarters in Richardson, Texas. Digital products such as models and setups are processed in the Digital Lab and delivered back to the practice through the same connection.

Information is transported back and forth between the practices and OraMetrix through a process called replication. Replication occurs as needed throughout each day. This means that replication can reconcile updates made on the same day. For example, if the Digital Lab delivers a Diagnostic Model to a practice on the same day the practice submits another scan of the same patient to OraMetrix, these records are merged and reconciled as part of the replication process.

2.3 Treatment Planning Software

Computers owned by the practice can be set up to access SureSmile patient records if they meet SureSmile's minimum software, networking, and other system requirements. See the DOC-500290-1 *System Requirements: SureSmile Treatment Planning Software* for more information.

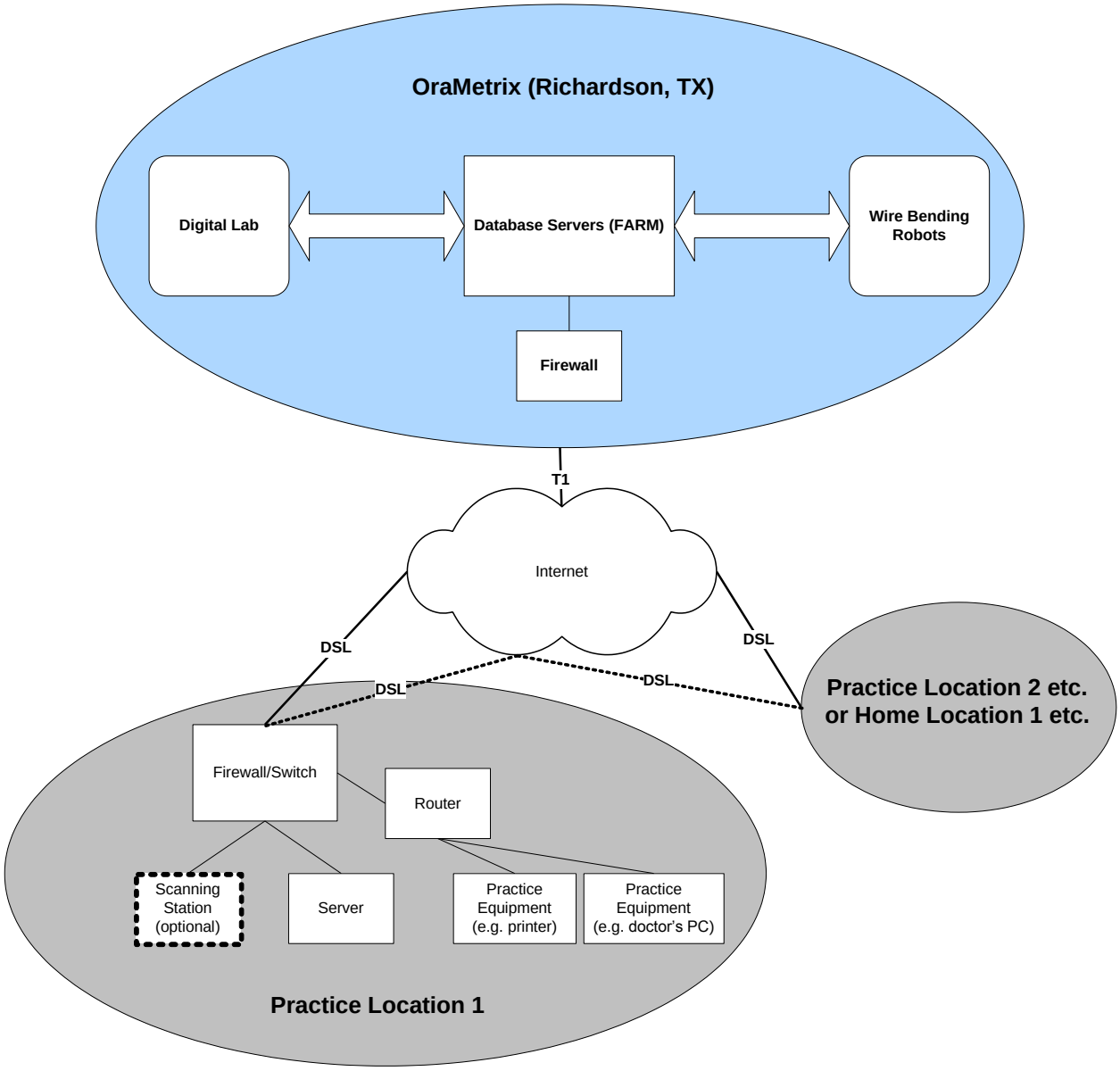


Figure 1: SureSmile System Diagram

2.4 Scanning Station

The Scanning Station is a mobile cart containing a computer and the OraScanner intraoral scanning device. The Scanning Station allows intraoral scanning of patients at chairside. It is connected to the SureSmile Server via a network and consists of the following components:

- Computer, keyboard, and mouse
- Isolation transformer
- Network isolator
- OraScanner with fiber-optic cable
- LCD flat panel display with touch screen
- Articulated arm for monitor
- Stylus
- Foot switch

NOTICE	The OraScanner unit is not intended for use as an operative device and is not manufactured to be sterile.

The touch screen monitor is connected to the cart on an adjustable arm. The OraScanner is held in a holster and is connected to the station with a fiber-optic cable. Adjacent to the OraScanner, a stylus is supplied as the pointing device to use with the touch screen. This is more effective and sanitary than using gloved fingers. Alternatively, you can use the computer mouse to interact with the scanning software. A wireless footswitch is also used to run the OraScanner.

CAUTION	It is very important to be careful with the fiber-optic cable. Do not bend, pinch, or crimp the cable. Do not pull the OraScanner to move the Scanning Station.

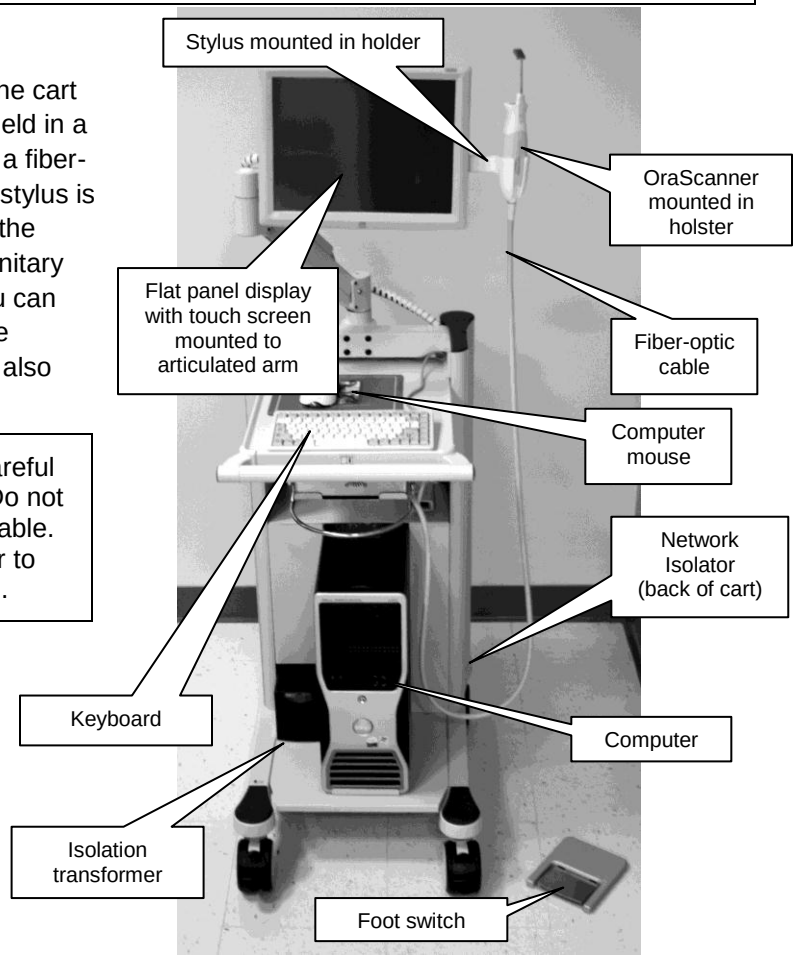


Figure 2: SureSmile Scanning Station Components

2.4.1 Scanning Station Connections

The connections of the different Scanning Stations are as shown below.

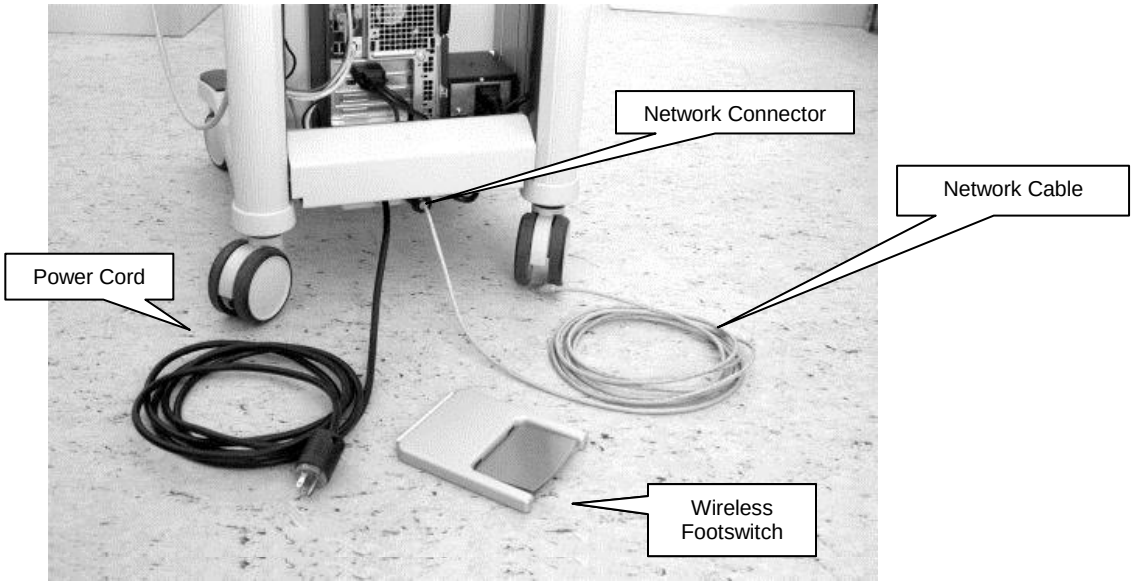


Figure 3: Connections on the US and Canadian Scanning Station

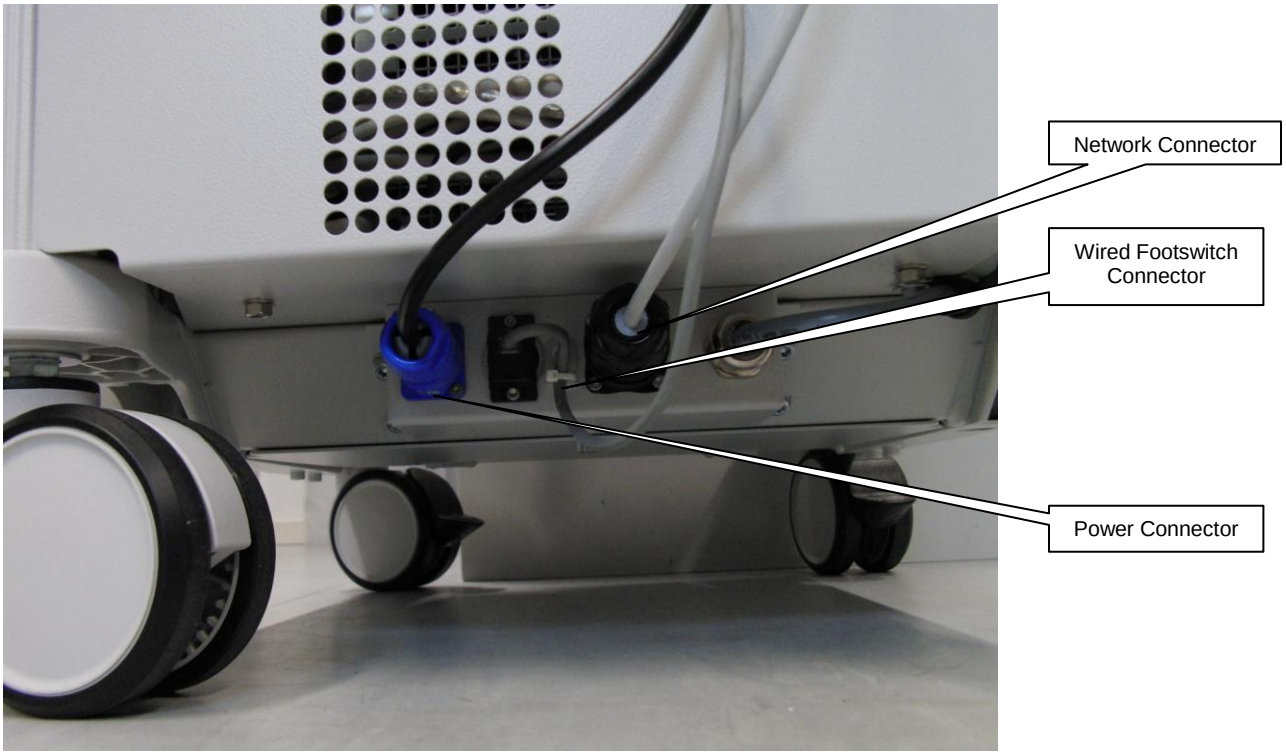


Figure 4: Connections on the Australian Scanning Station

2.4.2 Turning the Scanning Station On/Off

For technical reasons, OraMetrix may request that you turn off the power to the Scanning Station. The Main On/Off switch is located on the left side of the cart (Figure 5).

To turn off the Scanning Station:

1. On the **File** menu, click **Exit** to exit the SureSmile software.
2. In the logon dialog, click **Options >>**.
3. Click **Shutdown** and follow the on-screen instructions for shutting down the computer.
4. Locate the Main On/Off switch on the side of the cart.
5. Move the Main On/Off switch from 1 (On) to 0 (Off).

To power up the Scanning Station:

1. Locate the Main On/Off switch on the side of the cart.
2. Move the Main On/Off switch from 0 (Off) to 1 (On).
3. Press the computer power button.

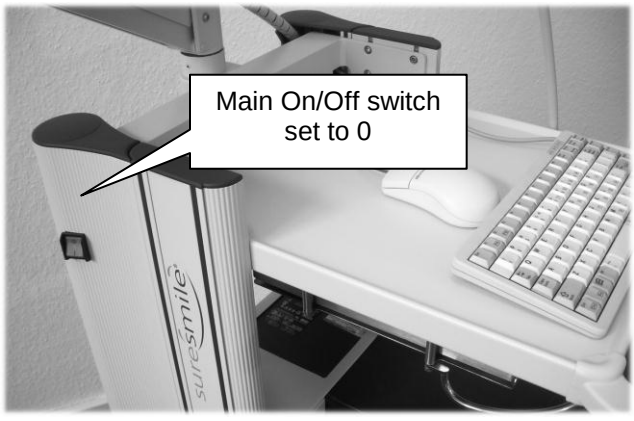


Figure 5: Location of Main On/Off switch

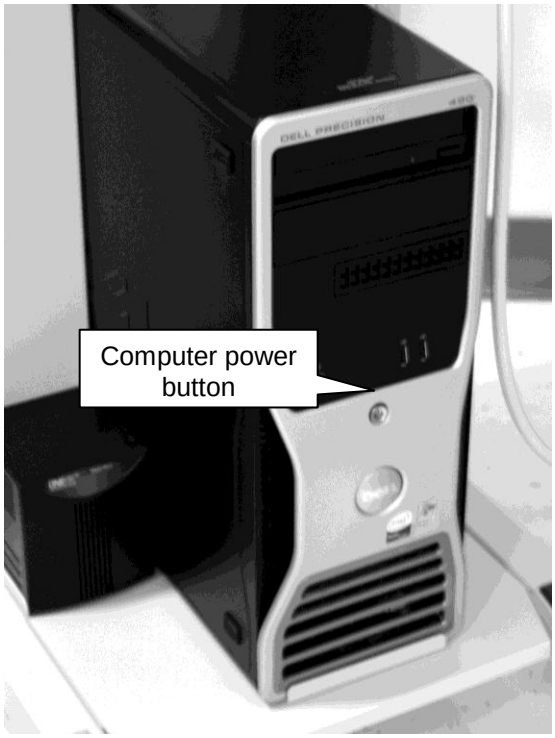


Figure 6: Front view of Scanning Station

2.4.3 Monitor

2.4.3.1 Contrast/Brightness

For optimal viewing of models and other images on the monitor, you may need to adjust the monitor's brightness and contrast. When the monitor is ideally adjusted, you should be able to clearly see the color variation of shadows on model teeth. If you do not see any color variation, or if the images are flat or fuzzy, use the controls on the monitor to adjust brightness and contrast. If these adjustments do not improve image quality, contact SureSmile Customer Care.

NOTICE	Tip: See the "Camera Navigation" topic in the SureSmile online help for instructions on how to change the lighting in the 3-D modeling pane in the SureSmile software.

2.4.3.2 Adjusting the Monitor

CAUTION	Do not hang anything from the Scanning Station monitor's extension arm. Adjust the extension arm gently. Take care with the OraScanner cable when moving the monitor.

The monitor can be moved up and down, left and right, and tipped down and up as shown in Figure 7 below. When moving the monitor and arm, be careful not to disconnect cables.

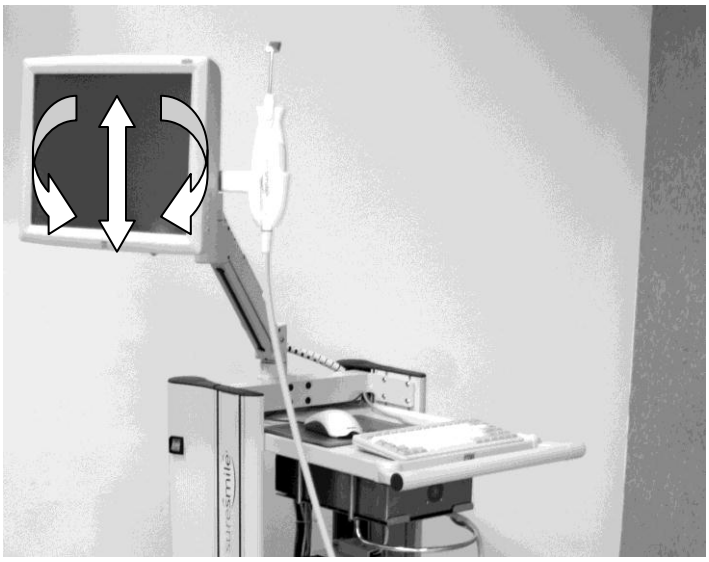


Figure 7: Monitor adjustment

2.4.4 Moving the Scanning Station

CAUTION	Use caution when moving the SureSmile System equipment. These precision-measuring devices should be handled with care.

	Failure to follow proper transportation procedures may result in damage to the system and risk personal injury. Connect the Scanning Station to hospital-grade power outlets only.

Office personnel may move the Scanning Station short distances within the office for cleaning or minor office layout changes.

To move the Scanning Station a short distance within the office:

1. Power down the Scanning Station.
2. Position the monitor between the two side columns of the cart (Figure 8).

Figure 8: Monitor position for cart movement

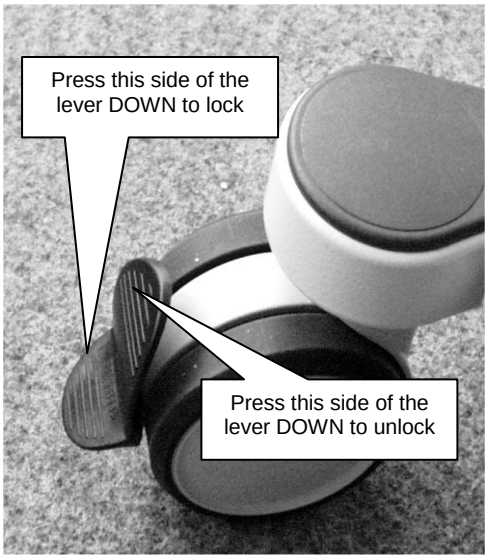


Figure 9: Caster brakes

3. Remove the networking cable from the wall outlet.
4. Remove the power plug from the wall outlet.
5. Unlock the caster brakes (Figure 9).
6. Carefully roll the cart to the new location.
7. Lock the caster brakes.
8. Plug the power cord into the new wall outlet (hospital-grade receptacles only).
9. Plug the network cable into the networking outlet. The system is now available for use.

2.5 OraScanner

2.5.1 OraScanner Performance

- Measurement uncertainty – less than 0.05 mm
- Depth of field – up to 10mm (see Figure 11).
- Center of focus – approximate midpoint of depth of field

2.5.2 How the OraScanner works

Attached to the Scanning Station with a fiber-optic cable, the OraScanner consists of a handheld unit with a detachable mirror, (Figure 10).

Figure 10: SureSmile OraScanner

When inserted into the unit, the OraScanner mirror extends into the patient's mouth to maximize visibility of the dentition. The mirror is heated to prevent fogging from the patient's breath. After scanning, the OraScanner mirror is detached for disinfection.

The OraScanner is a 3-dimensional (3-D) camera and high precision measuring instrument. The handheld unit contains a video camera coupled with a projector. Flashes of white light are reflected from the mirror at the end of the OraScanner onto the teeth. Between flashes of white light, a second flash bulb is used to project a color-encoded pattern that bends across the curves of the dentition. Similar to flash photography, the image of the pattern is captured at the same time the light flashes. Each image consists of hundreds of points connected into a 3-D wireframe to form a model.

It only takes a few minutes to perform a scan of an arch. As you capture images intraorally, the model (or digital impression) is built on-screen.

In Figure 11 and Figure 12, notice that the focus of the OraScanner is directly below the mirror. The yellow (shaded) areas indicate the path of the light between the camera, the mirror, and the teeth. Be careful not to block this path with the anterior teeth or lips. Figure 11 and Figure 12 also depict the depth of field and the center of focus, indicating the correct distance to position the OraScanner mirror in relation to the teeth.

CAUTION	The operator and patients should not look directly into the flashing light.

Figure 11: OraScanner Light Path

NOTICE	Do not block the projection or camera indicated by the yellow areas.

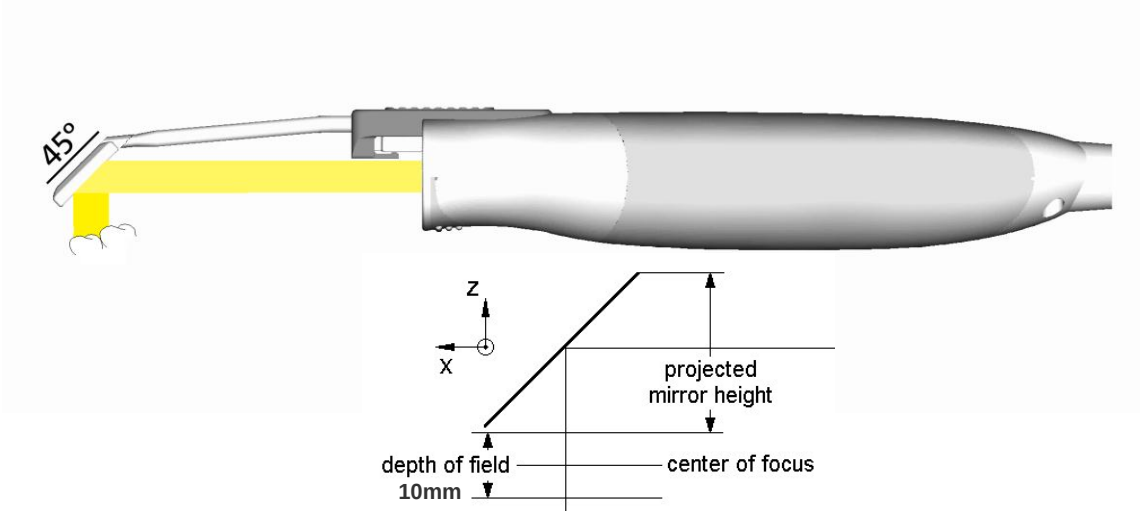


Figure 12: OraScanner Refraction Angle

2.6 SureSmile Server and network infrastructure equipment

WARNING	Do not place the Server and the network infrastructure in the patient contact area. It is not designed, tested, or specified for use in the patient contact area.
NOTICE	Depending on the supplier's product cycle, your equipment may vary from the version depicted; however similar connections and controls will be available. For detailed information, see the manuals of the manufacturers (Dell and Cisco).

The SureSmile Server should remain powered up to enable patient files to be replicated to OraMetrix.

The server and network infrastructure equipment is usually installed in a server room or near the high-speed Internet connection. It consists of the following components:

- Computer Server and Uninterruptible Power Supply (UPS) (Figure 13)
- Firewall (Figure 14)
- Monitor, Keyboard and Mouse (optional)

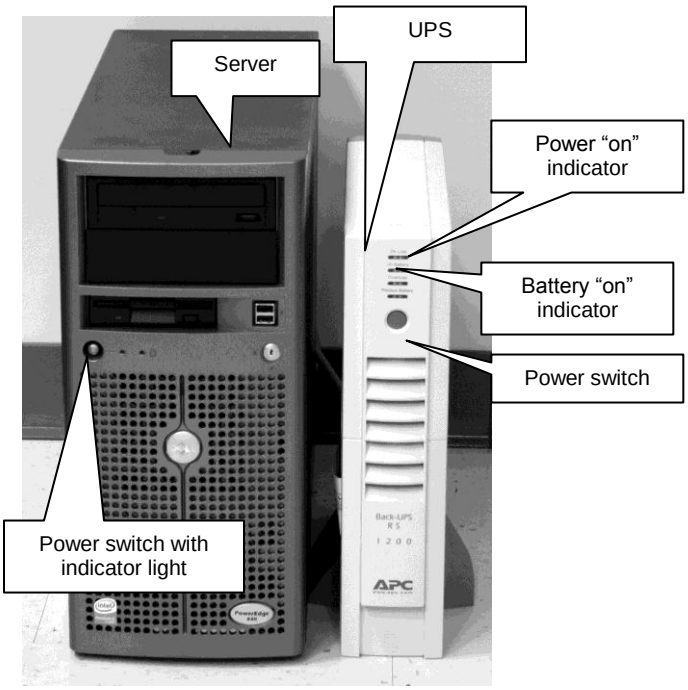


Figure 13: SureSmile Server, UPS

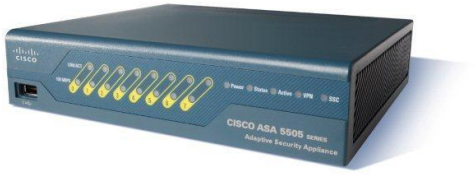


Figure 14: Firewall with router

2.7 Equipment Maintenance

It is the responsibility of the operator to perform a routine disinfection, storage, and maintenance procedure according to the respective hygienic policy of the clinic and in order to extend the useful life of the equipment.

2.7.1 Following a Maintenance Routine

OraMetrix recommends the following maintenance routines in your office. The operator should perform the following tasks.

2.7.1.1 Before Each Use

- Clean the front window and the OraScanner mirror as needed with the optical cloths provided.
- Visually inspect the OraScanner mirror for any obvious signs of wear or damage.

2.7.1.2 After Each Use

- Disinfect the OraScanner mirror.
- Disinfect the touch screen stylus.
- Disinfect the handheld portion of the OraScanner, the holster, cord, and the Scanning Station shelf top.
- Change the barrier tape on the computer mouse. OraMetrix recommends the Patterson Brand Universal Cover Sheet.

2.7.1.3 Daily

- Visually inspect the OraScanner mirror and the entire Scanning Station for any obvious signs of wear or damage.
- Clean the OraScanner mirror mount area of the handheld unit as described on page 20.

2.7.1.4 Weekly

- For optimum software operations, reboot the Scanning Station regularly. Reboot weekly or reboot every five scans, whichever occurs first.
- Inspect the power and LAN cables for wear or damage.

CAUTION	Before using any disinfectant, read the instructions from the manufacturer.

2.7.2 Cleaning the OraScanner Mirror

You will be supplied with multiple OraScanner mirrors. The OraScanner mirror consists of a mirror and neck mounted in a base, which clips to the hand-held unit. Clean it after each patient use.

To clean the OraScanner mirror:

1. Carefully remove the OraScanner mirror by pulling it away from the OraScanner.

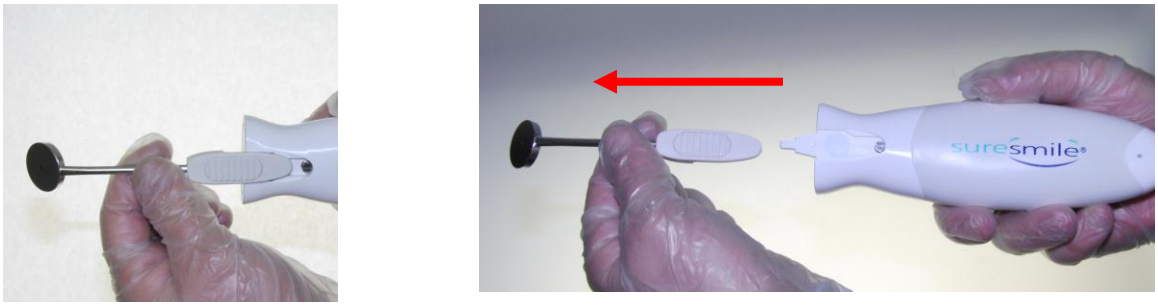


Figure 15: Removing the OraScanner Mirror

2. Disinfect the OraScanner mirror according to the respective hygienic policy of your practice. OraMetrix has tested the OraScanner mirror with disinfecting solutions. The mirror material is compatible with the following solutions:

- Banicide®
- Cidex® OPA Solution
- Cidexplus®
- PdCare®
- ProCide-D™
- SPOROX II

CAUTION	OraMetrix only guarantees compatibility of the mirrors with the specified disinfectant solutions.
	Avoid soaking the mirror with other instruments that may scratch or damage it.
	Do not soak the OraScanner mirror in these solutions past the manufacturer's recommended time for a high-level disinfection. It is not necessary to soak the OraScanner mirror to the point of sterilization. Additionally, soak times past 90 minutes may degrade the mirror, potentially causing risk to the patient.
	Do not sterilize an OraScanner mirror in an autoclave.
	Do not place the OraScanner mirror in an ultrasonic cleaning unit. Ultrasonic cleaning will erode the mirror adhesive over time.
NOTICE	These high-level disinfectants are specifically produced for heat-sensitive medical devices. The method of cleaning the OraScanner mirror is similar to that for cleaning other intraoral mirrors; however, the OraScanner mirror is more vulnerable to scratching due to its high-tech surface coating that enables a very high light reflection.

3. Rinse the OraScanner mirror with water and gently dry it with an optical cloth.

NOTICE	Do not skip this step for the following reasons: • Removes the chemicals for the patient's safety. • Removes the film the disinfectant often leaves on the mirror that interferes with scanning, and can erode the base mount reducing the lifespan of the OraScanner mirror significantly.

4. Place the OraScanner mirror in a location where the mirror will not become contaminated or damaged.

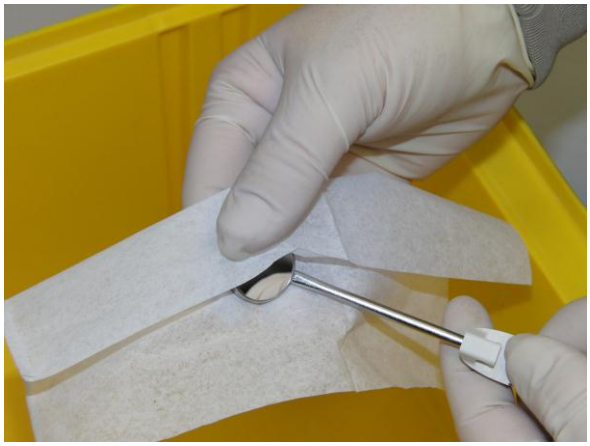


Figure 16: Cleaning the Mirror

CAUTION	Be careful not to scratch the mirror.

2.7.3 Cleaning the Scanning Station

Follow the manufacturer's instructions for the disinfecting solution used by your office to properly disinfect the Scanning Station. Remember to disinfect the OraScanner holster and cable, and any other surfaces in contact with the patient.

2.7.4 Cleaning the OraScanner

To clean the OraScanner:

1. Apply a spray disinfecting solution to a paper towel according to the hygienic policy of the clinic. Wipe down the handheld portion of the OraScanner.
2. Wipe the OraScanner front window with an optical cloth as shown (Figure 17).

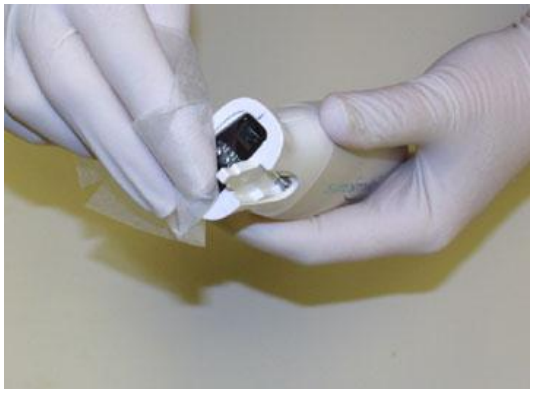


Figure 17: Cleaning the OraScanner Front Window

To clean the OraScanner mirror mount:

1. Carefully remove the OraScanner mirror from the OraScanner.
2. Dip a cotton swab into alcohol (isopropanol or ethanol) and rub it over the area (Figure 18). Keeping the area clean will extend the life of the clips connecting the OraScanner mirror to the OraScanner hand-held unit.

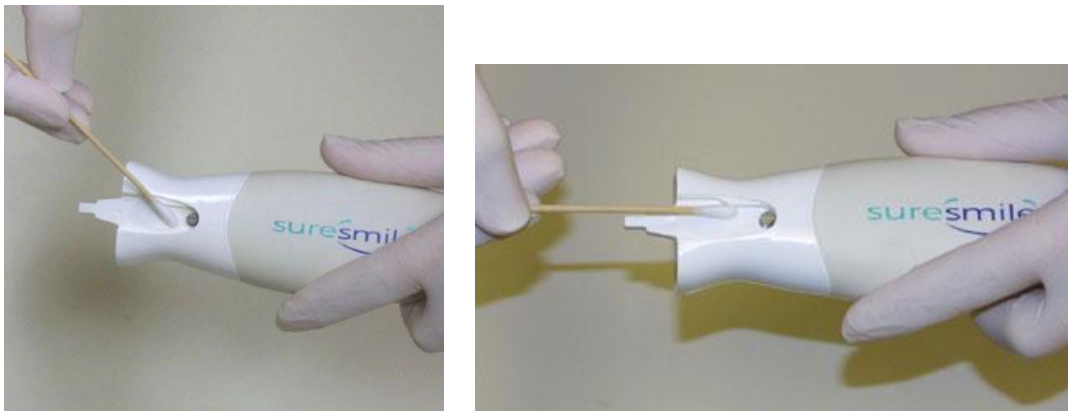


Figure 18: Cleaning the OraScanner Mirror Mount

3. Technical Addendum

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The Scanning Station is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanning Station should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF-emissions CISPR 11	Group 1	The Scanning Station uses RF for the operation of its wireless footswitch only at the frequency 914.5 MHz. Its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF-emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The Scanning Station is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Voltage fluctuations complies Flicker not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Emissions The Scanning Station is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanning Station should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV Contact ± 8 kV Air	± 6 kV Contact ± 8 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for I/O lines (input/output)	± 2 kV for Power supply lines ± 1 kV for I/O lines	Main power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in UT) for 0,5 cycle 40% U_T (60% dip in UT) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U T) for 5 s	< 5% U_T (> 95% dip in UT) for 0.5 cycle 40% U_T (60% dip in UT) for 5 cycles 70% U_T (30% dip in U T) for 25 cycles < 5% U_T (> 95% dip in UT) for 5 s	Main power quality should be that of a typical commercial or hospital environment. If the user of the Scanning Station requires continued operation during power main interruption, it is recommended that the Scanning Station be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC Main voltage prior to application of the test level.			

Recommended separation distance between portable and mobile RF communications equipment and the Scanning Station

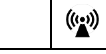
The Scanning Station is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Scanning Station can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitter) and the Scanning Station as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter (watts)	**Separation distance according to frequency of transmitter power of transmitter (meters)**		
	150 kHz to 80 MHz **$d = 1.2\sqrt{P}$**	**80 MHz to 800 MHz** **$d = 1.2\sqrt{P}$**	**800 MHz to 2.5 GHz** **$d = 2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: To calculate the recommended separation distance of transmitters in the frequency range at 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to include the possibility of disturbances caused by the unintentional introduction of mobile or portable communication equipment into the patient area.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The Scanning Station is intended for use in the electromagnetic environment specified below. The customer or the user of the Scanning Station should assure that it is used in such an environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Scanning Station (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM/FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Scanning Station is used exceeds the applicable RF compliance level above, the Scanning Station should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Scanning Station.

b Field strengths should be less than $[V_{1}]_{V/m}$ over the frequency range 150 kHz to 80 MHz,

3.1 Environmental and Storage Conditions

The SureSmile System components are suitable for use in a standard office environment.

Environmental Parameter Scanning Station		US / Canadian version	European / Australian version
Power line	Voltage range	120 V AC	230 V AC
	Voltage tolerance	+6.5% / -10%	+6.5% / -10%
	Frequency range	60 Hz	50 Hz
	Power connector	NEMA 5-15	Removable power cord with country-specific plug
	Frequency tolerance	+/- 5 Hz	+/- 5 Hz
	Total harmonic distortion	10%	10%
Power line transient susceptibility	Surge energy rating (one time, 10/1000 us waveform)	According to IEC 60601-1-2	
	Surge current capability (one time, 8/20 us waveform)	According to IEC 60601-1-2	
Temperature	Operating	From +10° C to + 30° C or 50° F to 86° F	
	Storage (non-operating)	From -15° C to +45° C or 5° F to 113° F	
Humidity	Operating outside of mouth	18 – 80% RH, non-condensing	
	Operating inside mouth	95% RH	
	Non-operating soak	90% RH for 90 hours at 65°C or 149°F	
Altitude	Operating	3 km or 1.86 miles	
	Storage (non-operating)	4.6 km or 2.86 miles	

Refer to the manufacturer's manual for environmental and storage conditions for equipment such as the SureSmile Server, UPS, and Firewall.

The image acquisition process may be influenced by high levels of electromagnetic interference (EMI).

The OraScanner is protected against EMI generated by devices that meet the limits of FCC part 15 class A/B.

3.2 Regulatory Information

The versions of the SureSmile System meet the appropriate requirements of the respective markets.

The Scanning Station has been tested to meet the requirements of IEC60601-1 for safety, and the requirements of IEC60601-1-2 for Electromagnetic Compatibility and Electromagnetic Immunity.

The OraScanner mirror is the only applied part in the SureSmile System and is galvanically isolated from all other system components. The OraScanner handheld is designed as IP54.

SureSmile System is classified as follows:

3.2.1 USA

The SureSmile System has been accepted by the FDA as a Class I medical device.

The Scanning Station has been tested to meet the safety requirements of UL60601-1.

3.2.2 Canada

The SureSmile System has been accepted by Health Canada as a Class I medical device.

The Scanning Station has been tested to meet the requirements of UL60601-1 for safety.

3.2.3 EU

According to the Medical Device Directive (MDD), the SureSmile System is a Class I medical device with measuring function.

The respective components are CE marked. The declaration of conformity is available on demand.

CE

3.2.4 Australia

The SureSmile System has been accepted by the Therapeutic Goods Administration (TGA) as a Class I medical device with measuring function.

4. Glossary

Customer Care Customer service department of OraMetrix providing technical and sales support.

Digital Lab Located at OraMetrix' headquarters, it includes all of the departments that process scans, develop 3D models, and fill archwire prescription orders for doctors.

OraScanner A handheld, intraoral camera used to capture 3-D images of a patient's dentition.

OraScanner Mirror A removable part of the OraScanner, the mirror reflects light onto the teeth and images back to the camera.

Patient Contact Area The area within your clinic, including the patient chair and surrounding 1.5 meters.

Scanning Station The entire chair-side unit that operates the OraScanner, including a cart, computer, monitor, and OraScanner.

SureSmile Complete Package SureSmile system configuration that includes one or more Scanning Stations.

SureSmile Server Networked with the Scanning Stations in the practice, the server-class computer on which patient data is stored.

SureSmile Service Package SureSmile system configuration that does not include a Scanning Station; typical installed when a practice has access to a SureSmile-certified CBCT Scanner.

SureSmile Process All of the SureSmile procedures encountered by a patient from beginning to end of treatment, including scanning, treatment planning, and archwire customization.

Technical Maintenance Maintenance operations that can only be done by qualified personnel according to the requirements of OraMetrix; for example, leakage current measurement, and change of UPS battery.

Notes

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